WRP Asia Pacific Sdn Bhd

147817V

K030157

FEB 19 2003

510(k) SUMMARY

1.0 Submitter:

Name:	WRP Asia Pacific Sdn Bhd
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Date of Summary Prepared: 14 JAN 2003

2.0 Contact Person:

Name:	Mr. Terence Lim
Phone No.:	+60 3 8706 1486
Fax No.:	+60 3 8706 1485

3.0 Device Identification:

Trade Name:	1) Comfit, and 2) Multiple or Customers' Trade Name
Device Name:	Powder Free Latex Examination Gloves, Sterile with Protein Content Labeling Claim
Common Name:	Examination Gloves
Classification Name:	Patient Examination Gloves (per 21 CFR 880.6250)

4.0 Identification of the Legally Marketed Device:

Class I patient examination gloves, 80LYY, powder free, that meets all the requirements of ASTM standard D 3578 – 01a^{E2} and FDA 21 CFR 800.20.

5.0 Description of the Device:

The Powder Free Latex Examination Gloves, Sterile with Protein Content Labeling Claim is equivalent to the existing model, i.e. Comfit Sterile Latex Examination Gloves (Powder Free) which had submitted and cleared under 510(k) number K944141.

The difference in this submission is:

a) To include Protein Content Labeling Claim statements on label, i.e.
"This latex glove contains 50 micrograms or less of total water extractable protein per gram" and
"Safe use of this glove by or on latex sensitised individuals has not been established".

The device remains no change in product design and the additional claim does not affect the intended use of the device as well as it does not affect its safety and effectiveness. The indication for use and proposed labeling for the device are illustrated in subsequent sections.

The Powder Free Latex Examination Gloves, Sterile with Protein Content Labeling Claim meets all the requirements of ASTM standard D 3578 – 01a^{E2} and FDA 21 CFR 800.20.

6.0 Intended Use of the Device:

The Powder Free Latex Examination Gloves, Sterile with Protein Content Labeling Claim is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

7.0 Summary of Technological Characteristics for the Modified Device:

The Powder Free Latex Examination Gloves, Sterile with Protein Content Labeling Claim are summarized with the following technological characteristics compared to ASTM or equivalent standards.

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE
Dimensions	ASTM D 3578 – 01a^{E2}	Meets
Physical Properties	ASTM D 3578 – 01a^{E2}	Meets
Freedom from pinholes	ASTM D 3578 – 01a^{E2} FDA 21 CFR 800.20	Meets
Powder Residual	ASTM D 6124 – 01	Meets < 2 mg/glove
Protein Level	ASTM D 5712-95	< 50 µg/g

8.0 Conclusion:

The Powder Free Latex Examination Gloves, Sterile with Protein Content Labeling Claim will perform according to the glove performance standards referenced in section 7 above and meet ASTM standards, and FDA requirements for waterleak test on pinhole AQL. Consequently, this device is substantially equivalent to currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 19 2003

Mr. Terence Lim
Associate Manager, RA/QA
WRP Asia Pacific Sdn. Bhd.
Lot 1, Jalan 3, Kawasan Perushaan,
Bandar Baru Salak Tinggi,
43900 Sepang, Selangor Darul Ehsan,
MALAYSIA

Re: K030157
Trade/Device Name: Powder Free Latex Examination Gloves, Sterile with Protein Content Labeling Claim (50 Micrograms or Less)
Regulation Number: 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LYY
Dated: January 14, 2003
Received: January 16, 2003

Dear Mr. Lim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

WRP Asia Pacific Sdn Bhd

147817V

INDICATIONS FOR USE

Applicant: WRP Asia Pacific Sdn Bhd

510(k) Number (if known): K030157

Device Name: POWDER FREE LATEX EXAMINATION GLOVES, STERILE WITH PROTEIN CONTENT LABELING CLAIM (50 MICROGRAM OR LESS)

Indications For Use:

The Powder Free Latex Examination Gloves, Sterile is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K030157